

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
*Southern Division***

| | | |
|--------------------------------|---|-----------------------|
| Hospira, Inc. | * | |
| Plaintiff, | * | |
| v. | * | |
| Sylvia Mathews Burwell, et al. | * | Case No. GJH-14-02662 |
| Defendants. | * | |

* * * * *

**MOTION FOR SUMMARY JUDGMENT REVERSING
AND VACATING AGENCY DECISION**

Pursuant to Rule 56, plaintiff Hospira, Inc. (“Hospira”) respectfully moves for summary judgment on both claims in Hospira’s complaint. The material facts are not in dispute and Hospira is entitled to judgment as a matter of law. The Court should reverse and vacate the final agency action of the defendant U.S. Food and Drug Administration (“FDA”) in Docket No. FDA-2014-N-0087 (decision issued August 18, 2014). Administrative Record 000804-000819. FDA’s decision in Docket No. FDA-2014-N-0087 is arbitrary, capricious, and contrary to law as (1) the decision violates 21 U.S.C. § 355(j)(2)(A)(viii)), and (2) the decision announces a substantive rule which FDA did not promulgate properly in accordance with the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* In support of this motion, Hospira relies upon the Administrative Record and the attached memorandum. For the reasons set forth in that memorandum, FDA’s decision in Docket No. FDA-2014-N-0087 should be reversed, vacated, and held to be of no legal force or effect. A proposed Final Judgment and Order is attached.

Respectfully submitted,

Dated: August 29, 2014

/s/ Ralph S. Tyler
Paul F. Strain (Bar No. 01255)
pfstrain@venable.com
Ralph Tyler (Bar No. 01747)
rtyler@venable.com
John A. McCauley (Bar No. 05031)
jmccauley@venable.com
Maggie T. Grace (Bar No. 29905)
mtgrace@venable.com
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
(410) 244-7400
Fax: (410) 244-7742

Attorneys for Plaintiff Hospira, Inc.